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EXAMINER

TUNG, JOYCE

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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The response filed 1/27/09 to the Office action has been entered. Claims 34 and 39-44 and 46-55 are pending.

1. Claims 34, 39-44, 47-48, and 52-55 remain rejected under 35 U.S.C. 102(e) as being anticipated by Lupski et al. (5,691,136, issued Nov. 1997) as evidenced by New England BioLabs catalogue.

Regarding claims 34, 39-44, 52 and 54, the response indicates that Fig. 3 of Lupski et al. depicts primers for the ERIC consensus whereas Fig. 2 depicts primers for the REP consensus and the alleged evidence of primers with constant and random portion is misguided. It is true that the primers of Fig. 2 and 3 are for different targets. However, each primer set has a constant portion and a random portion, for example, in fig. 2, primers REP1R-I, REP1R-D and REP1R-Dt have a constant portion, GG near the 3' end and a random portion near the 5' end, IGC1 for REP1R-I, GCGC or ACGT or ACGC or GCGT for REP1R-D and NCGN for REP1R-Dt (see fig. 2). So do the primers in fig. 3. Each primer set has a constant portion and a random portion.

In addition it is true that the primer of Lupski et al. is specific to its target (repetitive sequence) and the set of primers as recited by the instant claims has its own specificity (target sequence).

The response argues that Lupski et al. fails to teach "wherein the constant portion of each primer has the same nucleotide sequence". As discussed above, all primers REP1R-I, REP1R-D and REP1R-Dt have a constant portion, GG and all primers, REP2-I, REP2-D and REP2-Dt have a constant portion, TT near the 5' end (see fig. 2). These portions are interpreted as the constant portion of each primer having the same nucleotide sequence.

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The response also discusses “N” residues of Lupski et al. which are inosine residues within the REP consensus primer and this is not a random portion complementary to the target as claimed. The response further argues that the phrase "random portion" is defined in the specification on page 12, lines 18-25. However, the statement on page 12, lines 18-25 is not a definition of "random portion", but rather relates to an example of how primers having random or partially random sequence may be used. Thus the phrase "random portion" is not defined in the specification, and this language is reasonably interpreted to be covered by the teachings of Lupski et al.

The response also discusses the degeneracy of the probes of Lupski et al. to argue that primers in fig.2 do not have a “random portion” and that one of skill in the art would have known that the degenerate sequences are not, by definition, designed to be complementary to the target and instead, they represent a position at which they properly complementary sequence is not known. However, each primer has its own specificity.

Since the phrase "random portion" is not defined in the specification, the portions in the primers of Lupski et al. in fig.2 which are various are interpreted as a random portion, for example, a random portion near the 5' end, IGCI for REP1R-I, GCGC or ACGT or ACGC or GCGT for REP1R-D and NCGN for REP1R-Dt (see fig. 2). Therefore, the teachings of Lupski et al. read on the limitations of the claims.

Regarding claims 47-48, 53 and 55, the response argues that the teachings of Lupski et al. do not disclose that all of the primers in the set of primers are complementary to the same strand of the target sequence. Lupski et al. teach applying pairs of primers for the detection reaction in which multiple primers bind to different targets or where the primers of the primer pairs bind to

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the same portion (overlapping) of the same hybridization target (see Lupski et al., fig. 2 and 3).

The claims recite “wherein the complementary portions of each of the primers in the primer set are each complementary to a different portion of the hybridization target, wherein all of the primers in the set of primers are complementary to the same strand of the target sequence” (claim 47). Because the specification does not define “a different portion”, and the primers in figs 2 and 3 have different sequences, it is interpreted that the primer is able to hybridize to different sequences (overlapping) of a target sequence. These overlapping sequences are interpreted as different portions of a hybridization target.

The response argues that “the same strand of the target sequence” does not include the complementary strand of the target sequence. The limitations discussed herein are not required in the claims.

The response argues that Lupski et al. do not disclose the recitation of claim 47 that the set of primers has 3 or more primers wherein all primers in the set of primers are complementary to the same strand of the target sequence. In fig. 2, there are 3 primers in a set and in fig 3 there are 4 primers in a set. Specifically, the language “a set” is not defined in the specification. The group of primers, REP1R-I, REP1R-D and REP1R-Dt in fig.2 are interpreted as “a set”.

Based upon the analysis above, the teachings of Lupski et al. read on the limitations of the claims. The rejection is maintained.

2. Claim 49 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Lupski et al. (5,691,136, issued Nov. 1997).

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The response argues that Lupski et al. employs pairs of primers in the detection. Since the specification does not define "a set", any primers in a group are interpreted as a set as recited in the claim. Thus, the limitations discussed herein are not commensurate with the scope.

In addition, the response restates the same issues as discussed in the 102(e) rejection. With the same reasons as set forth above, the rejection is maintained.

3. Claims 46, and 50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lupski et al. (5,691,136, issued Nov. 1997) as applied to claims 34, 39-44, 47-48, and 52-55 further in view of Blanco et al. (Journal of Biological Chemistry, 1989, Vol. 264(15), pg. 8935-40).

Since the response argues the same issues as argued in the 102(e) rejection, with the same reasons as set forth above, the rejection is maintained.

Summary

4. No claims are allowable.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Joyce Tung/
Examiner, Art Unit 1637
March 27, 2009